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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/645,863	08/20/2003	Jonathan C. Heller	29191-707	7685
21971	7590	12/10/2004	EXAMINER	
WILSON SONSINI GOODRICH & ROSATI			DEJONG, ERIC S	
650 PAGE MILL ROAD			ART UNIT	
PALO ALTO, CA 943041050			PAPER NUMBER	
			1631	

DATE MAILED: 12/10/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/645,863

Applicant(s)

HELLER ET AL.

Examiner

Eric S. DeJong

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1 and 3-43 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1 and 3-43 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |  |
|---|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)            |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date ____ | 6) <input type="checkbox"/> Other: ____  |

## **DETAILED ACTION**

### **FIRST SPECIES ELECTION**

This application contains claims directed to the following patentably distinct species of the claimed invention:

Species of phenotype as set forth in claims 6, 11, 32, 33, 34, 35, 36, 37, 38, 39 and 40 are distinct and separately published in literature thus demonstrating an undue burden if searched together. Applicants are to elect one of the following species of phenotype: A) drug response phenotype, B) drug resistance phenotype, C) disease stage phenotype, D) disease recurrence phenotype, E) disease state phenotype, F) treatment selection phenotype, G) disease diagnostic phenotype, H) drug toxicity phenotype, I) adverse drug response phenotype, or J) an unspecified phenotype with respect to those listed above.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently claims 1, 3-5, 7-10, 14-31, and 41-43 are generic.

### **SECOND SPECIES ELECTION**

This application contains claims directed to the following patentably distinct species of the claimed invention:

Species of marketing as set forth in claims 4, 21, and 26 are distinct and separately published in literature thus demonstrating an undue burden if searched together. Applicants are to elect one of the following species of marketing diagnostic

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products: K) marketing diagnostic products that are kits, L) marketing diagnostic products includes marketing a mass spectrometry system, or M) marketing diagnostic products along with a disposable microfluidics device

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently claims 1, 3, 5-20, 22-25, and 27-43 are generic.

### **THIRD SPECIES ELECTION**

This application contains claims directed to the following patentably distinct species of the claimed invention:

Species of entities collecting samples as set forth in claims 7 and 10 are distinct and separately published in literature thus demonstrating an undue burden if searched together. Applicants are to elect one of the following species of sample collection:

N) a collaborator collects samples or O) an unspecified entity collects samples with respect to that listed above.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently claims 1, 3-6, and 14-43 are generic.

### **FOURTH SPECIES ELECTION**

This application contains claims directed to the following patentably distinct species of the claimed invention:

Species of markers as set forth in claims 15 and 16 and markers deemed species of the claims due to the listing in the specification on page 4, paragraph 0012 are distinct and separately published in literature thus demonstrating an undue burden if searched together. Applicants are to elect one of the following species of markers: P) polypeptides, Q) small molecules, R) nucleic acids, S) polysaccharides, T) metabolites, U) lipids, or V) an unspecified markers with respect to those listed above.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently claims 1, 3-14, and 21-43 are generic.

#### **FIFTH SPECIES ELECTION**

This application contains claims directed to the following patentably distinct species of the claimed invention:

Species of sample preparation preceding a mass spectrometry platform as set forth in claim 25 is distinct and separately published in literature thus demonstrating an undue burden if searched together with a generic method. Applicants are to elect one of the following species of sample preparation preceding a mass spectrometry platform: W) an unspecified sample preparation step preceding electrophoresis followed by a mass spectrometry platform or X) the step of preparing samples on a microfluidics device preceding the step of using a mass spectrometry platform.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently claims 1, 3-6, 12-24, and 26-43 are generic.

Applicant is advised that a reply to these requirements must include an identification of the species that are elected consonant with these requirements, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

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A telephone call was made to Peter Eng on December 7<sup>th</sup>, 2004 to request an oral election to the above restriction requirements, but did not result in an election being made.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric S. DeJong whose telephone number is (571) 272-6099. The examiner can normally be reached from Monday through Friday during the hours of 8:30AM to 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-0722. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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Ardin H. Marschel 12/9/04  
ARDIN H. MARSCHEL  
PRIMARY EXAMINER